

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS AND AMENDMENTS**

Claims 1-10 were pending in this application when last examined.

Claims 1-10 were examined on the merits and stand rejected.

Claims 1, 9 and 10 are amended herein to clarify the invention. Support for these amendments may be found in claims 1-4 as filed and in paragraph [0012] spanning pages 6-7 of the Specification.

No new matter has been added.

**II. NOVELTY REJECTION**

Claims 1-2, 4-5 and 8 are rejected under 35 USC 102(b) as being anticipated by Simon et al. Applicants respectfully traverse this rejection as applied to the amended claims.

Claim 1 has been amended to specify that the claimed process for purification of CMP-NeuAc yields a purity of 95% or more, and to incorporate the subject matter of claims 2-4. Applicants respectfully note that Simon et al. does not teach that the method referenced by the Examiner for this rejection can reach this level of purity.

As described in paragraph [0009] on pages 4-5 of the Specification, through addition of a divalent cation species to a CMP-NeuAc-containing solution, the claimed invention provides CMP-NeuAc having a purity of 95% or more, which had never been achieved by conventional techniques in the art, such as the methods referenced by the Examiner in Simon et al.

Since addition of such divalent cations does not affect the reaction of phosphatase, this enzyme may be added after addition of a divalent cation (i.e., step (1) followed by step (2)) as recited in claim 2, or this sequence may be reversed (i.e., step (2) before step (1)) as recited in claim 3. Also, steps (1) and (2) may be performed simultaneously. In contrast, according to the process of Simon et al., CMP-NeuAc is purified by use of NH<sub>4</sub>OH, ethanol, etc., followed by the addition of phosphatase and MgCl<sub>2</sub>, and then the addition of ethanol (the second addition). Such

a process is different from the claimed invention, which requires addition of a divalent cation species during the initial stage of purification.

Therefore, Applicants respectfully submit that this rejection is untenable for reasons which are self-evident and should be withdrawn.

### III. OBVIOUSNESS REJECTION

Claims 1-10 are rejected under 35 USC 103(a) as being unpatentable over Simon et al. in view of Warren et al. and Vann et al. Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that the level of purity of CMP-NeuAc produced by the claimed invention (95% or more) is comparable to that obtainable from chromatography, with a precipitation method that is much simpler than chromatography (see paragraph [0012], pages 6-7 of the Specification). Indeed, Simon et al., on page 7161, left column, last full paragraph, admit that the best means for purifying CMP-NeuAc is ion chromatography using iron exchange resin, with the differential precipitation method being considered secondary. Applicants submit that this assertion of Simon constitutes a teaching away from precipitation methods, such as that of the claimed invention, for attaining levels of purity as high as 95%.

It follows that one skilled in the art, such as Simon, would not expect that the simple precipitation method of the claimed invention could produce CMP-NeuAc that is 95% or more pure, without the use of purification steps such as chromatography, etc. Thus, the purity results (95% or more) obtained by the claimed invention would be unexpectedly high to one skilled in the art.

Turning to the cited references of Warren et al. and Vann et al., Applicants submit that they only refer to the requirement of Mg and Mn ions in the enzymatic reactions for producing CMP-NeuAc. These references fail to disclose what effect the addition of a divalent cation species would exert on purification of CMP-NeuAc.

Thus, the claimed invention achieves an unexpectedly high purity through addition of a divalent cation species to a CMP-NeuAc-containing solution, comparable to the purity obtainable from chromatography, albeit with a method simpler than chromatography. Further, of the cited references, Simon et al. represents a teaching away from the method of the claimed

invention, while Warren et al. and Vann et al. do not speak to the effect of the addition of divalent cation species on purification of CMP-NeuAc.

For these reasons, Applicants respectfully submit that one skilled in the art would have no reason to combine or modify the cited references to arrive at the claimed invention, nor any reasonable expectation of success in doing so. As such, this rejection is untenable and should be withdrawn.

**CONCLUSION**

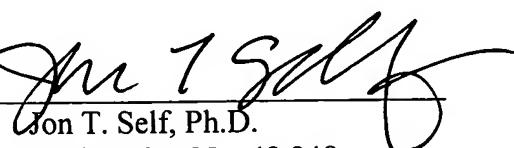
In view of the foregoing Amendments and Remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Tomoki HAMAMOTO et al.

By



Jon T. Self, Ph.D.

Registration No. 48,948

Attorney for Applicants

WMC/JTS/clw  
Washington, D.C. 20005-1503  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
December 8, 2009